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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/503,559	02/11/2000	Roland Valdes JR.	1160.033US1	6803

21186 7590 07/02/2003

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[REDACTED] EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
1648	[REDACTED]

DATE MAILED: 07/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/503,559	VALDES ET AL.
	Examiner	Art Unit
	Ulrike Winkler	1648

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 April 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 10-34 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-9 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>12</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>15</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

The Amendment filed April 15, 2003 (Paper No. 13) in response to the Office Action of October 6, 2003 is acknowledged and has been entered. Claims 1-9 are currently being examined. Applicant's affirmation of the Election/Restriction requirement is acknowledged.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Applicant is reminded that the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Examiner Ulrike Winkler**, Group Art Unit 1648.

Information Disclosure Statement

An initialed copy of Applicant's IDS Paper No. 15 is attached to the instant Office Action.

Claim Objections

The objection of claims 2 and 4 is withdrawn in view of applicant amending the claims to spell out the source of the dho.

Claim Rejections - 35 USC § 112

The rejection of claims 1-9 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is maintained** for reason of record.

Applicant's response has been thoroughly considered but is not persuasive. The thrust of the response is that Dh-OLF and dho represent distinct compounds. However, applicant own disclosure in the specification on page 26, lines 10-13 "the Dh-OLF isolated herein at fraction 27.5 showed an identical chromatographic retention to the standard component dho-B." The plant derived dho comprises two isomers two dho isomers; dho-A and dho-B. For purposes of the instant office action plant derived dihydroouabain is interpreted to fall within the scope of the definition of the "dihydroouabain-like factor", because it does contain both isomers.

Claim Rejections - 35 USC § 102

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Klaus Repenning (U.S. Pat. No. 3,113,128). Applicant's arguments and the submitted 37 CFR 1.132 declaration have been fully considered but they fail to persuade. Applicants own admission on the record see page 26, lines 10-13 indicates that "the Dh-OLF isolated herein at fraction 27.5 showed an identical chromatographic retention to the standard component dho-B" while the declaration directly contradicts the specification by indicating that the two compounds have different elution patterns. Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how

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the amendments avoid such references or objections. Therefore, the instant rejection is maintained for reason of record.

New rejection in view of applicant's amendments to the claims:

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Qazzas et al. (Abstract FASEB Journal 1997, see applicant IDS).

The instant claims are drawn to a compound which by virtue of the amendment indicate (specifically see claim 2) the dho-B derived from plant source is the same as the Dh-OLF derived from the mammalian source.

Qazzas et al. disclose the purified isomer of the plant-derived dho-B. Chemical compounds and their properties are inseparable, therefore, the limitation of the mammalian source does not distinguish instant invention over the prior art. See *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

Therefore, the instant invention is anticipated by Qazzas et al.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Ulrike Winkler, Ph.D.

James C. Housel
JAMES HOUSEL 6/30/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600